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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,018	06/27/2001	Alessandro Sette	2060.0320003	7107
50710	7590	12/02/2005		
STERNE, KESSLER, GOLDSTEIN & FOX, P.L.L.C. 1100 NEW YORK AVE. WASHINGTON, DC 20005			EXAMINER ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,018

Applicant(s)

SETTE ET AL.

Examiner

Marianne P. Allen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-32, 34, 36, 58, 59 and 61-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-32, 34, 36, 58, 59 and 61-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/9/2005 has been entered.

Claims 74-80 have been newly introduced. Claims 27-32, 34, 36, 58-59, and 61-80 are under consideration by the examiner.

Information Disclosure Statement

The information disclosure statements submitted 9/9/05 and 10/19/05 have been considered and the initialed forms are attached.

Specification

Applicant is requested to update the status of applications referenced throughout the specification. See for example pages 25 and 56.

Claim Rejections - 35 USC § 112

Claims 27-32, 34, 36, 58-59, and 61-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Original claims 27 and 28 had a step of sorting the epitope nucleic acids to minimize the number of junctional epitopes. Independent claims 72 and 73 are not original claims.

This sorting step was removed from claims 27 and 28 in a prior amendment and was not included in claims 72 and 73 when newly presented. There does not appear to be any basis in the specification for a method that does not sort the epitopes to minimize the number of junctional epitopes. In fact, the preamble goal of the claims is to design optimized multi-epitope polypeptides and this sorting step appears to be what results in the optimization. As presently written, while the preamble discusses optimization, the body of the claim has no optimization steps.

Although claims 58 and 61 include the sorting step, the order of the steps does not appear to be supported. That is, logically one would select the epitopes, sort them, and then construct the multi-epitope polypeptide or nucleic acid encoding it. The specification does not appear to disclose sorting and then selecting.

Basis for new claims 74-80 as well as previously presented claim 59 is not seen in any of the sections pointed to by applicant. There does not appear to be basis for methods comprising these steps.

Claims 28-31, 62-63, and 68-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-31, 62-63, and 68-80 are confusing by continuing to use abbreviations in the claims. While claim 27 was amended to set forth the amino acid identities (e.g. "lysine (K)"),

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only the proline in independent claim 28 was corrected. Various claims use abbreviations (see for example, claims 62, 63, 72, 73) and new claims 77 and 78 use abbreviations.

Claims 75 and 76 are confusing. Claims 62 and 63 produce a second polypeptide in addition to the polypeptide in claims 27 and 28, respectively. However, claims 75 and 76 incorporate all of the epitopes into one polypeptide. These claims are confusing in their dependency as they do not contain all of the limitations of claims 62 and 63, respectively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27, 32, 34, 36, 59, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergmann et al. (Reference NPL151).

Bergmann et al. discloses a multi-unit CTL epitope polypeptide and corresponding minigenes where two CTL epitopes were selected and linked by flanking or spacer sequences such as GG, AA, AG, GA, and K. Both epitopes were produced by the HLA processing pathway. See at least abstract and Figures 1-4.

As both epitopes were produced, the flanking or spacer amino acid residue can be considered to prevent the occurrence of a CTL junctional epitope.

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Claims 27, 59, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitton et al. (Reference NPL165).

Whitton et al. discloses a multi-unit CTL epitope polypeptide and corresponding minigenes where two CTL epitopes were selected and linked by flanking or spacer sequences such as GRT. Both epitopes were produced by the HLA processing pathway. See at least abstract and Figures 1-2.

As both epitopes were produced, the flanking or spacer amino acid residue can be considered to prevent the occurrence of a CTL junctional epitope.

Claims 27-29, 32, 34, 36, 62-63, 72-73, 75-76, and 77-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Sette et al. (U.S. Patent No. 6,689,363 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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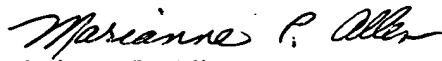
Sette et al. discloses linking multiple CTL and HTL epitopes by small spacer molecules such as Ala or Gly. The corresponding minigenes are also disclosed. The patent discloses designing multi-epitope constructs in order to avoid junctional epitopes. Four class I and four class II epitopes are disclosed as being incorporated into a minigene for expression. See at least abstract; column 32; Examples 9-10 at columns 43-45; Example 14 at column 47; and claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Marianne P. Allen
Primary Examiner
Art Unit 1647

mpa